Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte JAMES E. JERVIS

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Appeal No. 1999-2649
Application 08/483,291

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HEARD: February 7, 2001

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Before CALVERT, FRANKFORT, and BAHR, Administrative Patent Judges.

CALVERT, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 21, 23, 25 to 31, 34 to 38, 40 to 42 and 44 to 46. Claims 32, 33, 39 and 43 were also finally rejected, but the examiner states on page 2 of the answer that claims 32 and 33 are allowed, and

claims 39

and 43 were canceled by an amendment filed with appellant's brief.

The involved invention generally concerns medical devices made of shape memory alloys (SMA) which display the property of stress-induced martensite (SIM)[1]. The particular subject matter in issue is defined by the claims on appeal, which are reproduced in Appendix A of appellant's brief.

The references applied in rejecting the claims on appeal are:

Foster, Jr.	4,485,805	Dec. 4, 1984
Balko et al. (Balko)	4,512,338	Apr. 23, 1985
Middleman et al. (Middleman)	5,231,989 (filed Feb. 15, 1991)	Aug. 3, 1993

Schetky, Shape-Memory Alloys, 20 Kirk-Othmer Encyclopedia of

[1] At the oral hearing counsel for appellant pointed out that the statement in the first paragraph on page 13 of the brief, to the effect that appellant's memory alloy element does not require treatment to obtain SIM properties, is incorrect.

Chemical Technology 726-736 (3d Ed. 1982).[2]

The appealed claims stand finally rejected on the following grounds:

(1) Claims 21, 23, 25 to 31, 34 to 38, 40 to 42 and 44 to 46, unpatentable over Balko in view of Kirk-Othmer and Foster, under 35 U.S.C. § 103(a).

(2) Claims 21 and 23, unpatentable for obviousness-type double pantenting over claims 1 and 2 of Middleman.

(3) Claims 21 and 23, unpatentable over Middleman under either 35 U.S.C. § 102(e) or 103(a).

Rejection (1)

Balko discloses a medical device in which an element such as wire element 24 or 34 is carried within a sheath 20 or 36, and is released from the sheath at a desired position in a vessel 16, 30 or other body channel. The element is made of an SMA, such as Nitinol, which has a martensite transformation

[2] The examiner incorrectly refers to this reference as "Seader", which is the name of the author of a preceding entry. We will refer to it in this decision as "Kirk-Othmer."

temperature somewhat below or about body temperature (37EC). The temperature of the element is maintained below the transformation temperature until it is in position, as by using an insulating sheath. When the element is released from the sheath it is warmed by the body tissue to a temperature above its martensite transformation temperature, and reforms into its coiled form (col. 4, lines 13 to 27). Balko does not disclose that the SMA used displays SIM, but the examiner, citing Kirk-Othmer page 731, lines 13 to 20 [sic: 14 to 21], and page 733, line 6, takes the position that Nitinol can exhibit SIM (superelastic) properties, and therefore that the Nitinol disclosed by Balko would inherently have SIM properties at about body temperature.

The cited portion on page 731 of Kirk-Othmer reads:

> The other property peculiar to marmem alloys is the ability under certain conditions to exhibit superelastic behavior. Although in one sense, the 3-8% apparently recoverable strain of the memory effect is truly an extended or pseudoelastic behavior, an even further elastic range is possible. When many of the martensitic alloys are deformed well beyond the point of the initial single-coalesced martensite stage, a stress-induced martensite-martensite transformation can occur. In this mode of deformation strain is reversible through stress release and not by a temperature-

> induced phase change, and recoverable strains as high as 17% have been observed.

Page 733, line 6, states that an early medical device (an orthodontic brace) "exploits the superelastic behavior of Nitinol." We do not read these portions of Kirk-Othmer as disclosing that all Nitinol exhibits superelastic (SIM) properties, but only that "many" of the martensitic alloys do "when deformed well beyond the point of the initial single-coalesced martensite stage." This is consistent with the declaration of Dr. Middleman[3], a coinventor of the above-listed '989 patent, that (para. 11, pages 3 to 4):

> Although nitinol can exhibit the properties of an SIM material it can do so only if it undergoes a treatment process to make it exhibit the properties of an SIM material. This process requires an extensive, time consuming and expensive procedure.

In basing a rejection on the ground that the prior art would inherently possess a claimed property, the examiner bears the initial burden of establishing a prima facie case, as by showing that the claimed and prior art products are identical or substantially identical or are produced by

[3] Declaration of Dr. Lee Middleman under 37 CFR § 1.132, dated Feb. 2, 1998, filed Mar. 18, 1998.

identical or substantially identical processes. See, e.g., In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). In the present case, we consider the examiner's statement on page 8 of the answer that "both of Balko and [the] instant application use the nitinol alloy" to be overly broad. Balko specifically discloses the use of SMAs, particularly nickel-titanium alloys (nitinol), which "completely recover to their original shape on being raised to a higher temperature" (col. 3, lines 37 to 39), whereas appellant discloses the use of SMAs which display SIM properties, i.e., in which the shape change is "mechanically, rather than thermally, actuated and controlled" (specification, page 8, lines 13 to 16). The alloy preferred by appellant is nickel-titanium-vanadium, as disclosed in Quin Patent No. 4,505,767 (id., page 8, lines 22 to 24). As shown by Kirk-Othmer and the Middleman declaration, nitinol does not exhibit SIM properties unless it receives additional treatment, of which there is no suggestion in Balko. We therefore conclude that the examiner has not made out a prima facie case that the SMAs disclosed by Balko would inherently

display SIM properties.

The Foster patent contains no disclosure concerning SMAs, and was cited by the examiner only as evidence of the obviousness of using a guide wire (recited in claims 21, 37 and 38). In the view we take of this case, further consideration of Foster is unnecessary.

Each of independent claims 21, 26, 31 and 34 requires, in varying language, a memory alloy element (claim 21) or a stent (claims 26, 31 and 34) formed at least partly from an alloy which displays SIM behavior.

In view of the foregoing discussion, the combination of Balko and Kirk-Othmer would not have suggested or rendered obvious these limitations.

Moreover, claim 21, for example, additionally recites "wherein the alloy is selected so that the transformation can occur without any change in temperature of the placement device or the memory alloy element," and similar limitations are contained in the last three lines of claim 26, the last six lines of claim 31, and the last two lines of claim 34. Even if it were to be assumed that the nitinol disclosed by

Balko would exhibit some SIM properties, these limitations would not be met because Balko does not teach transformation without a change in temperature, but rather, Balko's entire disclosure is directed toward using an alloy which will transform when the temperature rises from below body temperature to body temperature (or when otherwise heated, see col. 5, lines 57 to 67).

Accordingly, rejection (1) will not be sustained.

Rejection (2)

The examiner asserts that claims 21 and 23 are obvious over claims 1 and 2 of the commonly-assigned Middleman patent.[4] According to the examiner, the "elongated tube" of patent claim 1 corresponds to the "hollow placement device" of claim 21, "elastic member" of patent claim 1 to the "memory alloy element" of claim 21, and the "straightening means" of patent claim 1 to the "guide wire" of claim 21.

Appellant argues that this rejection should be reversed

[4] Our understanding is that the Middleman patent and the present application are both currently assigned to Medtronic, Inc.

regardless of whether we apply the "one-way test" for obviousness-type double patenting (In re Goodman, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993)), or the more stringent "two-way test" (In re Braat, 937 F.2d 589, 593, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991)). Since we conclude that the rejection does not pass the "one-way test," the question of which test to apply is moot.

Considering the language of claims 1 and 2 of Middleman in relation to claim 21, we agree with the examiner that the "hollow placement device" recited in claim 21 is met by the "elongated tube" recited in claim 1, and the "memory alloy element" of claim 21 finds response in the "elastic member" recited in claim 1 (as modified by claim 2). However, claim 21 further recites "the hollow placement device stressing the memory alloy element . . . so that the memory alloy element is in its deformed shape," the "deformed shape" being "when the alloy is in its stress-induced martensitic state." There are no such limitations in claims 1 and 2 of the patent; rather, claim 1 recites the opposite, namely, "the elastic member [memory alloy element] being sufficiently stiff to cause the

distal segment [of the elongated tube (claim 21's “hollow placement device”)] to bend when the elastic member is in its bent shape,” the “bent shape” being defined in claim 2 as being “when the alloy is in its stress-induced martensitic state” (col. 17, lines 34 and 35). Since claim 21 requires that the hollow placement device stresses the memory element so that it is in its SIM state, while claims 1 and 2 of the patent require that the elastic member (memory alloy element) cause the tube (hollow placement device) to bend when the member is in its SIM state, i.e., that the tube does not stress the elastic member, we find no basis for concluding that the quoted limitations of claim 21 would be obvious over the structure recited in patent claims 1 and 2, or vice versa.

Rejection (2) therefore will not be sustained.

Rejection (3)

We will not sustain this rejection.

A reference does not qualify as prior art under 35 U.S.C. § 102(e)/103 unless it is a U.S. patent with an effective filing date prior to the effective filing date of the application. MPEP § 706.02(a), p. 700-11, col. 1, para. (A)

(Feb. 2000); see, e.g., In re Scheiber, 587 F.2d 59, 199 USPQ 782, (CCPA 1978). Here, appellant asserts at page 31 of the brief, and the examiner does not disagree, that the effective filing date of the claims on appeal is October 14, 1983,[5] a date well prior to the February 15, 1991, (effective) filing date of the Middleman patent. Since Middleman does not meet the § 102(e)/ § 103 prerequisite of having an earlier effective filing date it does not qualify as prior art under those sections of the statute, regardless of the fact that Middleman and the present application have a common assignee and different inventive entities, as noted by the examiner on page 11 of the answer.

[5] The filing date of application 06/541,852, the first in the chain of applications resulting in the present case.

Conclusion

The examiner's decision to reject claims 21, 23, 25 to 31, 34 to 38, 40 to 42 and 44 to 46 is reversed.

REVERSED

IAN A. CALVERT Administrative Patent Judge	)
CHARLES E. FRANKFORT Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
JENNIFER D. BAHR Administrative Patent Judge	)

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Jeffrey G. Sheldon
Sheldon & Mak
225 South Lake Avenue Suite 900
Pasadena, CA 91101